

# iLite<sup>®</sup> Cell-based Solutions

## REFERENCE LIST

### GUIDELINES

#### FDA (U.S. Food & Drug Administration)

Draft Guidance: [Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products](#). April 2016 Pharmaceutical Quality/CMC Revision 1.

Guidance for Industry: [Potency Tests for Cellular and Gene Therapy Products](#). January 2011

#### EMA (European Medicines Agency)

Draft guideline/ Guidance for Industry: [Immunogenicity assessment of biotechnology-derived therapeutic proteins](#). EMEA/CHMP/BMWP/14327/2006 Rev. 1.

[Guideline on development, production, characterisation and specification for monoclonal antibodies and related products](#). 21 July 2016 EMA/CHMP/BWP/532517/2008.

### PUBLICATIONS

**Lallemand C, Kavrochorianou N, Steenholdt C, Bendtzen K, Ainsworth MA, Meritet JF, Blanchard B, Lebon P, Taylor P, Charles P, Alzabin S, Tovey MG.** *Reporter gene assay for the quantification of the activity and neutralizing antibody response to TNF $\alpha$  antagonists.* J. Immunol. Methods. 373,229-239 (2011).

**Lallemand C, Meritet JF, Erickson R, Grossberg SE, Rouillet E, Lyon-Caen O, Lebon P, Tovey MG.** *Quantification of neutralizing antibodies to human type I interferons using division-arrested frozen cells carrying an interferon-regulated reporter-gene.* J. Interferon Cytokine Res. 28, 393-404 (2008).

**Lallemand C, Meritet JF, Erickson R, Lebon P, Tovey MG.** *Characterization of neutralizing antibodies to Interferon  $\beta$  using a novel gene-reporter assay: Neutralization titer is dependent upon specific activity of the Interferon  $\beta$  Subtype.* J Interferon Cytokines Res 28, 393-404 (2008).

**Ravnborg M, Bendtzen K, Christensen O, Jensen PEH, Hesse D, Tovey MG, Sorensen PS.** *Treatment with azathioprine and cyclic methylprednisolone has little or no effect on bioactivity in anti-interferon beta antibody-positive patients with multiple sclerosis.* Mult. Scler. 15, 323-328 (2009).

**Bendtzen K, Svenson M.** *Enzyme immunoassays and radioimmunoassays for quantification of anti-TNF biopharmaceuticals and anti-drug antibodies.* In: Tovey MG, editor. Detection and quantification of antibodies to biopharmaceuticals. Practical and applied considerations. West Sussex, UK: A. John Wiley & Sons, Inc; 2011. p. 83-101.

**Bendtzen K.** *Anti-TNF- $\alpha$  biotherapies: perspectives for evidence-based personalized medicine.* Immunotherapy. 4, 1167-1179 (2012).

**Steenholdt C, Ainsworth MA, Tovey M, Klausen TW, Thomsen O, Brynskov J, Bendtzen K.** *Comparison of techniques for monitoring infliximab and antibodies against infliximab in Crohn's disease.* Ther. Drug Monit. 35, 530-538, (2013).

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